IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	Robert E. Arbogast et al.	Confirm. No.:	4457
Application No.:	09/893,535	Examiner:	Dilek B. Cobanoglu
Filing Date:	06/29/2001	Art Unit:	3626
Title:	System, Method, And Computer Program Product For Configuring And Purchasing A Medical Device	Attorney Docket No.:	OHI 1717-008A

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/Vickie D'Alessandro/
Vickie D'Alessandro (paralegal)

APPELLANTS REPLY BRIEF UNDER 37 CFR § 41.41

Dear Sir:

The following remarks are in response to the Examiner's Answer mailed on September 24, 2007. Appellants respectfully request that the Board consider the following remarks prior to ruling on the present appeal.

REMARKS/ARGUMENTS

As explained many times during examination of the present application, the present invention (and the claimed subject matter) is directed to an automated system and method of configuring a multi-component medical device, such as a prosthesis, from a collection of individual medical device components. More specifically, based on one or a few criteria (typically patient attributes and/or desires), a system and method of the present invention can query one or more databases containing various medical device components, sort through the large number of available components for each component type of interest, (e.g., prosthetic sockets, prosthetic knee joints, prosthetic ankles, etc.), analyze the multitude of potential component combinations, and provide one or a number of acceptable prosthesis assemblies using various combinations of qualifying components of each component type. Such criteria may include, for example, patient weight, patient activity level, medical device cost, or medical device weight. Thus, a system and method of the present invention can greatly reduce the time required to configure a medical device comprising a plurality of individual components – a laborious process that would otherwise have to be performed manually by a practitioner.

As also explained many times during examination of the present application, Clynch (US 6,463,351) does not teach or suggest such a system or method. Rather, Clynch teaches a system and method for manufacturing a particular type of medical device *component* – a limb interface. More specifically, Clynch teaches a system and method by which a body part can be scanned and digitized so as to permit the

decentralized manufacturing of a custom limb interface. Such an interface may be, for example, a prosthetic socket or a rigid limb-abutting member of an orthotic brace. However, Clynch is concerned *only* with the manufacture of such specific components, which components account for only a portion of the overall prosthetic, orthotic or other device into which they are assembled. Clynch teaches nothing about configuring or assembling the remainder of the prosthetic, orthotic or other device that will make use of such a component. According to Clynch, the remainder of the configuration process would still need to be performed manually – which is exactly what the present invention seeks to overcome. Therefore, Clynch simply cannot be held to teach or suggest a system and method of the present invention, wherein *all* the components necessary to form a prosthetic, orthotic or other medical device may be automatically considered, evaluated, selected and assembled into one or more *complete* medical devices.

Specific Claim Rejections

As stated in its Appeal Brief, and throughout the prosecution of the present application, Appellants have repeatedly failed to find support for the Examiner's arguments at the cited sections of Clynch. The Examiner has not addressed Appellants' remarks or requests for clarification in this regard. Rather, the Examiner has simply repeated the citations and rejections in subsequent office actions. As the general and substantial differences between Clynch and the present invention have been clearly pointed out above and in previous communications, Appellants' comments below in regard to the Examiner's specific claim rejections will focus on the evident lack

of disclosure of the claimed subject matter in those sections of Clynch cited by the Examiner for such purposes.

Rejection of Claims 31-37, 39, 46-48, 65-67 and 82 Under 35 U.S.C. § 102(e)

The Examiner rejected claims 31-37, 39, 46-48, 65-67 and 82 under 35 U.S.C. § 102(e) as being anticipated by Clynch. Appellants respectfully maintain that said claims are allowable over Clynch.

Claim 31

- The Examiner asserts that the subject matter of claim 31 that reads

> *populating a digital repository with information corresponding to a plurality of medical device components*

is taught by Clynch at col. 4, ll. 49-53 and col. 7, l. 61 to col. 8, l. 10.[1] thereof. However, Clynch at col. 4, ll. 49-53 merely recites

> *The scan facility 12 is equipped with equipment for capturing a three dimensional optical image of a target surface, in converting the image into a digitized data file which provides data that may be displayed and manipulated on a computer workstation.*

Clynch at col. 7, l. 61 to col. 8, l. 10 merely recites

> *Each of these default modifications are stored in a database of imperically derived data based on prior successful medical devices. When a default modification is selected, the shape and location of the modification is displayed on the image and updated on the pull down*

[1] While the Examiner's Answer recites "… to col. 18, line 10", it is assumed that the Examiner meant column 8, as there is no column 18.

modification menu 62. Factors such as the regional shape, blending shape, operation and shift direction may be controlled using radio buttons. The vertical and horizontal blending range are also controllable using virtual dial wheels 66, 68 and the depth of the modification can be adjusted using a virtual dial wheel 70 in order to ensure that the modification conforms to the requirements of the patient. In addition, the size and shape of the modification can be manipulated using the computer's mouse by dragging coloured symbols indicating the borders of the region within which the modification will take place, the application area and the horizontal and vertical blending ranges surrounding the modification site.

➢ Neither of these cited sections of Clynch teach or suggest populating a digital repository with information corresponding to a plurality of *medical device components*. Clearly, the first of the Examiner's citations teaches only that a target surface can be scanned and converted into a 3-D model (data file). There is no teaching or suggestion of the claimed subject matter against which the cited section of Clynch is asserted. Further, from a reading of Clynch at col. 7, ll. 14-59, it can be understood that the default modifications recited in the Examiner's second citation are default CAD *software* modifications that may be selected by a user when manipulating a scanned body part image. The stored default modifications have nothing to do with medical device components, and certainly not to a digital repository of such components.

- The Examiner asserts that the subject matter of claim 31 that reads

interviewing a patient having a need for a medical device to determine at least one patient attribute

is taught by Clynch at col. 5, ll. 1-6. However, Clynch at col. 5, ll. 1-6 merely recites

In accordance with the method, the process of constructing a medical device begins in a physician's clinic 10 where in a step 20, a modelling material is fitted to the body part of a patient requiring a medical device. As described above, the medical device may be a prosthetic, orthotic, radiological or any other anthropometric precision fit device.

➢ This section of Clynch clearly fails to teach or suggest interviewing a patient having a need for a medical device to determine at least one patient attribute. In fact, there is absolutely no mention of any interviewing or questioning of the patient, or of any dialogue whatsoever between the physician and patient, in this section of Clynch. If the Examiner assumes such an interview to be inherent to every doctor/patient meeting, or that such an interview would be obvious, Appellants' assert that any such assumption is wholly improper and unsupported.

- The Examiner asserts that the subject matter of claim 31 that reads

storing the at least one patient attribute in a memory

is taught by Clynch at col. 6, ll. 36-40 and col. 9, ll. 7-12 thereof. However, Clynch at col. 6, ll. 36-40 merely recites

FIG. 2 shows the preferred arrangement of facilities for manufacturing medical devices using the method in accordance with the invention. A

> *plurality of clinics 10 are served by one or more scan facilities 12 which are in turn served by one or more manufacturing facilities 14.*

Clynch at col. 9, ll. 7-12 merely recites

> *The present invention provides a method for decentralizing most of the process of producing medical devices so that the majority of the work involved in the process of obtaining a modified digital image of the affected body part can be accomplished in a local physician's clinic to which the patient has ready access.*

➢ Appellants contend that neither of these cited sections of Clynch teach or suggest storing at least one patient attribute in a memory. These sections of Clynch simply teach that various clinics, scan facilities and manufacturing facilities may be in electronic communication so as to transmit data regarding a body part of interest therebetween. Neither of the cited sections, nor the drawing figure (Figure 2) referred to therein, mentions or depicts the storage of anything in memory. Nor is there any mention of a patient attribute.

- The Examiner asserts that the subject matter of claim 31 that reads

> *querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient.*

is taught by Clynch at col. 7, ll. 22-44 and 61-65, and col. 4, ll. 14-39 thereof. However, Clynch at col. 7, ll. 22-44 merely recites

The digitized scanned image 60 of the model is displayed in a window on the left hand side of the monitor. The modeled image shown is that of a below knee amputation, but any body portion may be imaged, including a foot, knee, leg, hip, back, shoulder, torso, arm, hand, neck or head for example. A pull down menu 62 is displayed in a window adjacent the scanned image. The pull down menu 62 includes the default options for modifying the scanned image to produce a mold to be used in the manufacture of the medical device or to produce a medical device directly from the modified image. The list of default modifications is available on a scrolling sub-menu 64. The options on the scrolling sub-menu depend on the type of medical device to be produced. Regardless of the type of device, a "uniform shrink" and a "smooth" option are available to permit the image to be uniformly shrunk in order to compensate for the thickness of the model and yield an accurately dimensioned image representative of the body part for which the device is to be produced. The smooth option converts the surface of the modified image into a smooth surface having the appearance of the mold that will be produced from the machine code generated from the modified image. Other options on the modification menu, as noted above, are device dependent.

Clynch at col. 7, ll. 61-65 merely recites

Each of these default modifications are stored in a database of imperically derived data based on prior successful medical devices. When a default modification is selected, the shape and location of the modification is displayed on the image and updated on the pull down modification menu 62.

Clynch at col. 4, ll. 14-39 merely recites

The physicians may be prosthetists, orthopedic surgeons, podiatrists, radiologists or plastic surgeons and other professionals may be industrial designers of custom protective gear, sports gear, or equipment for handicapped individuals. Each of these professionals at least periodically require or can benefit from the practice of the method in accordance with the invention. The prosthetists practice the invention to provide prosthetic devices such as artificial limbs. Orthopedic surgeons, orthotists, and podiatrists may practice the invention to provide orthotic devices such as braces and/or supports for weak or ineffective joints or muscles, including compression garmets to correct skeletal disorders such as scaliosis. Radiologists may practice the invention to provide locators and/or stabilizers for positioning patients requiring radiotherapy to ensure that patients are immobilized during a radiotherapy treatment and to ensure that radiation is accurately focused on the target tissue. Plastic surgeons may use the invention for designing implants and/or tracking and documenting the effects of

plastic surgery. The industrial designers may practice the invention for any anthropometric application, including the production of precision fit coverings to support or protect the human anatomy, such as custom seats for wheelchairs, etc. and protective or performance enhancing gear for sport or occupational activities including clothing, footwear, helmets or body armor and the like.

- There is absolutely no mention of a subset of medical device components, a digital repository of medical device components, or querying a digital repository for a subset of medical device components in col. 7, ll. 22-44 or 61-65 of Clynch. Rather, these sections of Clynch describe nothing more than digital image manipulation. (See also Fig. 3, referred to therein). Everything described in these sections of Clynch, and shown in Fig. 3, is related to a practitioner manipulating the digital image of the cast body part to produce areas of relief or build-up in the subsequently manufactured interface component. The referenced shrink and smooth operations, as well as the database storage of default modifications (i.e., pre-defined image changes), are all functions of software image manipulation. Even the language of lines 47-52 refers to modifications that may be made to the *digital image* of a body part in order to produce specific modifications to the finished interface component in the stated areas - *not* to *medical device components*. There is absolutely no discussion of medical device components, of a digital repository, or of the querying thereof. Also, there can be no subset of medical device components because Clynch is concerned only with a single component of a medical device. The database referred to in these sections stores only

information on previous changes made to similar digital body part (model) images, not information on medical devices. The disclosure of col. 4, ll. 14-39 also fails to teach the claimed subject matter against which said disclosure is cited. Rather, col. 4, ll. 14-39 of Clynch simply recites possible users and uses of the invention.

Claim 35

- The Examiner asserts that the subject matter of dependent claim 35 that reads

> *The method of Claim 34, wherein the ranking criteria is at least one of a weight of the medical device, a height of the medical device, a width of the medical device, a cost of the medical device, an activity level supported by the medical device, and an inventory status of the medical device.*

is taught by Clynch at col. 7, ll. 34-44. However, Clynch at col. 7, ll. 34-44 merely recites

> *Regardless of the type of device, a "uniform shrink" and a "smooth" option are available to permit the image to be uniformly shrunk in order to compensate for the thickness of the model and yield an accurately dimensioned image representative of the body part for which the device is to be produced. The smooth option converts the surface of the modified image into a smooth surface having the appearance of the mold that will be produced from the machine code generated from the modified image. Other options on the modification menu, as noted above, are device dependent.*

➢ Again, this section of Clynch wholly fails to teach or suggest the claimed subject matter against which it is asserted. There is absolutely no mention of ranking criteria of any kind. Furthermore, there is also no reference whatsoever in Clynch to the weight, height or width of a medical device, or to the activity level of an amputee that will use the medical device.

Claim 46

- The Examiner asserts that the subject matter of claim 46 that reads

  means for populating a digital repository with information corresponding to a plurality of medical device components

is taught by Clynch at col. 4, ll. 49-53, col. 7, ll. 61-63, and col. 4, ll. 14-39 thereof.

➢ See above comments regarding claim 31.

- The Examiner asserts that the subject matter of claim 46 that reads

  means for interviewing a patient having a need for a medical device to determine at least one patient attribute

is taught by Clynch at col. 5, ll. 1-6.

➢ See above comments regarding claim 31.

- The Examiner asserts that the subject matter of claim 46 that reads

  means for storing the at least one patient attribute in a memory

is taught by Clynch at col. 6, ll. 36-40 and 50-54 thereof.

➢ See above comments regarding claim 31.

- The Examiner asserts that the subject matter of claim 46 that reads

  means for querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient.

is taught by Clynch at col. 7, ll. 22-44 and 61-65, and col. 4, ll. 14-39 thereof.

➢ See above comments regarding claim 31.

Claim 65

- The Examiner asserts that the subject matter of claim 65 that reads

  populating a digital repository with information corresponding to a plurality of individual medical device components

is taught by Clynch at col. 4, ll. 49-53, col. 7, ll. 61-63, and col. 4, ll. 14-39 thereof.

➢ See above comments regarding claim 31.

- The Examiner asserts that the subject matter of claim 65 that reads

  populating a digital repository with patient historical information associated with a patient

is taught by Clynch at col. 9, ll. 7-12 thereof. However, Clynch at col. 9, ll. 7-12 merely recites

The present invention provides a method for decentralizing most of the process of producing medical devices so that the majority of the work involved in the process of obtaining a modified digital image of the

affected body part can be accomplished in a local physician's clinic to which the patient has ready access.

➢ This section of Clynch in no way teaches or suggests a digital repository, populating a digital repository, or the use of patient historical information. Rather, this section of Clynch merely teaches that manufacturing operations associated with a medical device component can be located in specialized facilities remote from a physician's clinic. This has nothing to do with a digital repository or populating a digital repository, and certainly does not teach the use of patient historical information.

- The Examiner asserts that the subject matter of claim 65 that reads

interviewing the patient having a need for a medical device to determine at least one patient attribute

is taught by Clynch at col. 5, ll. 1-6.

➢ See above comments regarding claim 31.

- The Examiner asserts that the subject matter of claim 65 that reads

storing the at least one patient attribute in a memory via a digital communication link

is taught by Clynch at col. 6, ll. 36-43 thereof.

➢ See above comments regarding claim 31.

- The Examiner asserts that the subject matter of claim 65 that reads

querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of

medical device components collectively forming a medical device meeting the need of the patient.

is taught by Clynch at col. 7, ll. 22-44 and 61-65, and col. 4, ll. 14-39 thereof.

➢ See above comments regarding claim 31.

- The Examiner asserts that the subject matter of claim 65 that reads

ordering the medical device over the digital communication link

is taught by Clynch at col. 3, ll. 12-14 thereof. However, Clynch at col. 3, ll. 12-14 merely recites

The three dimensional image is thereafter preferably downloaded to a computer system of the physician which produced the model.

➢ This section of Clynch is wholly unrelated to the claimed subject matter against which it is asserted. Rather, this section of Clynch merely teaches that the three dimensional image created by a scanning facility from a cast model of a body part is sent to the computer system of the practitioner that cast the body part. This disclosure has nothing whatsoever to do with ordering a medical device. In fact, Clynch cannot teach ordering a medical device because the system and method of Clynch can be used to produce only one component thereof. As such, a practitioner is left to configure and order the remainder of a prosthetic device by other means.

- The Examiner asserts that the subject matter of claim 65 that reads

storing information corresponding to the medical device in the digital repository associated with the patient

is taught by Clynch at col. 6, ll. 36-40 and col. 9, ll. 7-12 thereof.

- See above comments regarding claim 31.

As can be understood from the foregoing, Clynch fails to teach at least several elements of each of the rejected claims. Consequently, Appellants once again respectfully submit that Clynch cannot support a rejection of claims 31-37, 39, 46-48, 65-67 and 82 under 35 U.S.C. § 102(e).

Rejection of Claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 35 U.S.C. § 103(a)

The Examiner rejected claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 under 35 U.S.C. § 103(a) as being unpatentable over Clynch in view of DeBusk et al. (US 6,581,204). Appellants respectfully maintain that said claims are allowable over this combination of references cited as prior art by the Examiner.

Claim 1

- The Examiner asserts that the subject matter of claim 1 that reads

  a digital repository populated with entries defining a plurality of medical device components, each entry associated with an individual medical device component and having at least one patient attribute indicator

is taught by Clynch at col. 4, ll. 49-53 and col. 7, l. 61 to col. 8, l. 10 thereof.

- See above comments regarding claim 31.

- The Examiner asserts that the subject matter of claim 1 that reads

  a practitioner user interface mechanism configured to provide a practitioner with access to entries in the digital repository via a network

and to allow the practitioner to provide at least one patient interview answer indicator

is taught by Clynch at col. 5, ll. 1-6 and col. 6, ll. 40-43. However, Clynch at col. 5, ll. 1-6 merely recites

In accordance with the method, the process of constructing a medical device begins in a physician's clinic 10 where in a step 20, a modelling material is fitted to the body part of a patient requiring a medical device. As described above, the medical device may be a prosthetic, orthotic, radiological or any other anthropometric precision fit device.

Clynch at col. col. 6, ll. 40-43 merely recites

The clinics 10 preferably communicate with the scan facilities using a telecommunications service such as the Internet, graphically illustrated and indicated by reference 46.

- This section of Clynch clearly fails to teach or suggest a practitioner user interface mechanism configured to provide a practitioner with access to entries in a digital repository. In fact, there is absolutely no mention of a digital repository (or any type of repository), or any means by which such a repository may be accessed. Furthermore, and as discussed above, there is no disclosure in Clynch of any interviewing or questioning of the patient, or of any dialogue whatsoever between the physician and patient. Consequently, there can be no teaching or suggestion of allowing a practitioner to provide at least one patient interview answer indicator via said practitioner user interface mechanism.

- The Examiner asserts that the subject matter of claim 1 that reads

  a patient interview mechanism configured to receive over the network the at least one patient interview answer indicator corresponding to an attribute of a patient and to store the at least one patient interview answer indicator in a memory

  is taught by Clynch at col. 5, ll. 1-6 thereof.

➢ See preceding comment regarding claim 1, as well as above comments regarding claim 31.

- The Examiner asserts that the subject matter of claim 1 that reads

  a configurator mechanism configured to select a subset of entries from the digital repository based on the at least one patient interview answer indicator in the memory, the subset of entries including entries corresponding to individual medical device components that collectively form a medical device meeting a need of the patient.

is taught by Clynch at col. 7, ll. 22-44 and 61-65 thereof.

➢ See above comments regarding claim 31.

As DeBusk et al. appears to be nothing more than an advanced medical supply inventory tracking and management system and, as the Examiner appears to have cited DeBusk et al. only for its asserted disclosure of a component identification indicator, Clynch in view of DeBusk et al. still fails to teach or suggest at least the following elements of claim 1:

(1) *a digital repository* populated with entries defining a plurality of medical device *components*, the entries each associated with an *individual* medical device component;

(2) at least one *patient attribute indicator* associated with the entries;

(3) *a practitioner user interface mechanism* configured to provide a practitioner with access to entries in the digital repository via a network and to allow the practitioner to provide at least one *patient interview answer indicator*;

(4) *a patient interview mechanism* configured to receive over the network the at least one patient interview answer indicator corresponding to an attribute of a patient and to *store the at least one patient interview answer indicator in a memory*; and

(5) *a configurator mechanism* configured to *select a subset of entries from the digital repository* based on the at least one patient interview answer indicator in the memory, the subset of entries including entries *corresponding to individual medical device components* that *collectively* form a medical device meeting a need of the patient.

As can be understood from the foregoing, Clynch in view of Debusk et al. fails to teach at least several elements of each of the rejected claims. Consequently, Appellants once again respectfully submit that Clynch in view of Debusk et al. cannot support a rejection of claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81 under 35 U.S.C. § 103(a).

CONCLUSION

For at least the foregoing reasons, it is submitted that the Examiner's continued rejection of claims 1-39, 46-49, 65-69 and 80-82 is unsupported by the cited references.

As such, Appellants' respectfully request reversal of the Examiner's rejection of claims 1-39, 46-49, 65-69 and 80-82 and allowance of the present application.

Respectfully submitted,

Date: 11-26-2007

By: /Eric M. Gayan/

Eric M. Gayan
Attorney for Appellants
Registration No. 46,103
Standley Law Group LLP
495 Metro Place South
Suite 210
Dublin, Ohio 43017-5319
Telephone: (614) 792-5555
Facsimile: (614) 792-5536
E-mail:egayan@standleyllp.com